

**REMARKS**

Applicant respectfully requests the PTO to reconsider the present application.

**I. Disposition of the Claims**

Claims 1-5 and 63-68 are pending. Claims 6-62 were previously canceled. Claims 1-3, 5, and 63-68 are rejected. Claims 4 and 66 are objected to. Claims 67-68 have been withdrawn but should be rejoined when claim 1 is allowable. Claims 1-2 and 5 are currently amended, support for which is believed apparent.

The PTO is thanked for indicating allowable subject matter. Office action, p. 19.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claim 5 has been amended without disclaimer of the full scope of the "neurotrophic factor."

**II. Enablement Rejection**

Claim 5 was rejected, because the specification allegedly fails to have enabled "active truncated derivatives." Office action, pp. 4-9. The present version of claim 5 avoids the issue. Thus, the rejection should be withdrawn.

**III. Indefiniteness Rejection**

Claim 5 was rejected as indefinite, because the term "active truncated derivatives thereof" is undefined in the specification as-filed. Office action, pp. 6-9. The present version of claim 5 avoids the issue. Thus, the rejection should be withdrawn.

#### IV. Anticipation Rejection

Claims 3 and 65 were rejected as anticipated by example 1(A) of GB 1,503,244. Office action, pp. 9-10. According to the PTO, "Example 1(A) on page 6 is in water (e.g., a pharmaceutically acceptable carrier)." Office action, p. 10. But it is respectfully submitted that the issue is not whether water is a pharmaceutically acceptable carrier. Rather the issue is what GB 1,503,244 describes.

The cited example, in part, reads: "After cooling to room temperature, the resulting crystals were collected by filtration, washed with water, and recrystallized from **acetone-water**...." GB 1,503,244 at 6, ll. 21-25 (emphasis added). The acetone-water mixture is not necessarily pharmaceutically acceptable. Indeed, nothing in GB 1,503,244 indicates that the acetone-water mixture was made with pharmaceutically acceptable acetone or water.

The PTO, nevertheless, should not ignore any claim limitations, including the "pharmaceutically acceptable carrier." Thus, GB 1,503,244 never anticipates the pharmaceutical composition of claim 3 or 65, and the rejection should be withdrawn.

#### V. Obviousness Rejections

Claims 1-3 and 63-65 were rejected as allegedly prima facie obvious over the teachings of Wakabayashi (JP 52-083686), GB 1,503,244, and Jamieson (U.S. Pat. No. 4,230,709), each taken alone or in combination with each other when similar utilities are asserted. Office action, pp. 11-18. According to the PTO, "[o]ne skilled in the art would thus be motivated to prepare compounds embraced by the reference genera to arrive at the instant claimed products with the expectation of obtaining compounds which would be useful in treating, for example, asthma." Office action, p. 15. This rejection is improper and should be withdrawn.

The combination of teachings is improper, as combining references requires the desirability of the combination. MPEP § 2143.01. Yet the teachings of Wakabayashi, GB 1,503,244, and Jamieson are disparate. Wakabayashi concerns germicides (p. 1); GB 1,503,244 concerns compounds for fungicidal and herbicidal activity (p. 1); Jamieson concerns

compounds for treating asthma (col. 1). There is no reason of record to combine them. Thus, the rejection over the combination is improper and should be withdrawn.

Concerning the individual references, the PTO compared example 1(A) of GB 1,503,244 and the previous version of claim 2, which recited "(7aS) -2- (4 - (Trifluoromethyl) phenyl) perhydropyrrolo [1, 2-c] imidazole-1, 3-dione." It is respectfully noted that claim 2's present version lacks this compound. Furthermore, even if GB 1,503,244 were to teach an isomer of any compound of claim 3 or 65, that alone would not be enough to render that claim *prima facie* obvious. For example, it is respectfully submitted that there is no reason to add the cited compound, which according to GB 1,503,244 may have fungicidal and herbicidal activity, to a pharmaceutically acceptable carrier to form a pharmaceutical composition.

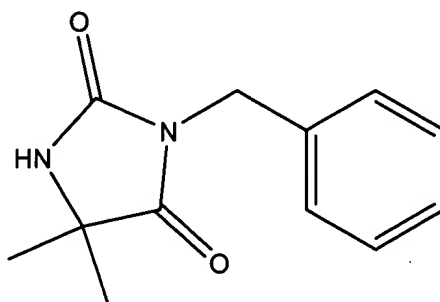
Similarly, the PTO compared example 1 of Wakabayashi and the compound deleted from the previous version of claim 2. For analogous reasons to those in the previous paragraph, it is respectfully submitted that there is no reason to add the cited compound, which according to Wakabayashi may be a germicide, to a pharmaceutically acceptable carrier to form a pharmaceutical composition.

Furthermore, the PTO compared the generic disclosure column 1, lines 20-54 of Jamieson and claim 3 of the present invention. According to the PTO, "'indiscriminately' selecting an embodiment of the claimed invention would produce a compound from the generic disclosure of Jamieson." Office action, p. 17. But the PTO must find some motivation or suggestion to make the claimed invention in order to establish a *prima facie* case. MPEP § 2144.08 II A. In other words, a *prima facie* case of obviousness is not established, even if a genus embraces a species. Id. ("These 'Genus-Species Guidelines' are to assist Office personnel in the examination of applications which contain claims to species or a subgenus of chemical compositions for compliance with 35 U.S.C. § 103 based upon a single prior art reference which discloses a genus encompassing the claimed species or subgenus but does not expressly disclose the particular claimed species or subgenus."). It is submitted that the proper test is outlined in MPEP § 2144.08 and that this test, if followed, would not result in the rejection of the present claims.

In the present case, the cited genus is too big to disclose every member. *Cf.* MPEP § 2144.08II.A.4.a. Thus, the cited genus fails to anticipate any particular species or subgenus.

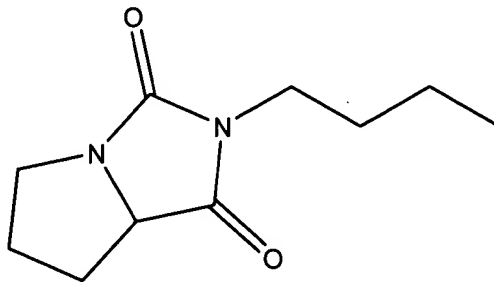
Nor, according to the evidence and explanation, does Jamieson expressly teach a particular reason to select any particular species or subgenus. *Cf.* MPEP § 2144.08II.A.4.b. In fact, Jamieson discloses a genus, allegedly novel genus (A)-(C) (col. 1, l. 55-col. 2, l. 6), and then examples. Neither a subgenus nor a species is mentioned as better than another.

Furthermore, cited example 6 discloses 3-benzyl-5,5-dimethyl-2,4-imidazolidine-dione, which according to ChemDraw, is



3-Benzyl-5,5-dimethyl-2,4-imidazolidine-dione

(Compound 6), and cited example 8 discloses 2-n-butyl-tetrahydro-1H-pyrrolo[1,2-c]imidazole-1,3-(2H)-dione, which, according to ChemDraw is



2-n-Butyl-tetrahydro-1H-pyrrolo[1,2-c]imidazole-1,3-(2H)-dione.

The first compound is not a hydantoin. The second compound is outside the scope of claim 1 (see first proviso).

Furthermore, no reason from Jamieson exists to modify its teachings in a way needed to reach a compound of claim 1. *Cf.* MPEP § 2144.08II.A.4.c. Jamieson states "compounds in which R<sup>3</sup> is C<sub>1-4</sub> alkyl such as n-butyl are preferred." Jamieson, col. 2, ll. 6-7. As a result, Jamieson teaches to limit its R<sup>3</sup> and to vary Jamieson's other substituents, e.g., R<sup>1</sup>, R<sup>2</sup>, and R<sup>4</sup>.

It is submitted that the evidence of record and explanation lack the required motivation. As a result, the record and explanation lack a reasonable expectation of success. Each rejection is improper and should be withdrawn.

**Conclusion**

Each claim is believed to be in condition for allowance. Favorable reconsideration is respectfully requested. The Examiner is invited to contact the undersigned attorney by telephone if it is felt that a telephone interview would advance the prosecution of the present application.


The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

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By



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